

- 10 -

REMARKS1. Status of the Claims

Claims 1-46 were originally filed in the present application. Claim 23 and 24 were withdrawn from consideration by the Examiner. Claims 1-22 and 25-46 are presently subjected to a restriction requirement set forth in the Office Action mailed March 16, 2004 (hereinafter the "Action"). Claims 2, and 30 are canceled herein without prejudice or disclaimer. Claims 47-50 are added herein. Therefore, claims 1, 3-29, and 31-50 are currently pending in the present application. Support for the amendments to claims 13 and 40 can be found throughout the specification and in claim 1. Support for new claims 47-50 can be found throughout the specification and in claims 6, 15, 16, and 20, respectively.

Reconsideration of the present restriction requirement is respectfully requested in view of the amendments above and the remarks below.

2. Restriction is Required Under 35 U.S.C. 121 and 372

The Examiner asserts that the invention allegedly contains inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The present restriction requirement is respectfully traversed for reasons of record and as follows.

Applicants hereby elect without traverse the invention of claims 1-46 directed to Formula II (SEQ ID NO:122). Claims 1 and 29 are amended herein and claims 2 and 30 are canceled herein to reflect the election of Formula II (SEQ ID NO:122) without traverse. Applicants reserve the right to pursue the non-elected subject matter (including claims directed to Formula I and SEQ ID NO:120 (8-17)) in a continuing or divisional patent application. As required by the Examiner, Applicants hereby elect, with traverse, SEQ ID NO:121, corresponding to the core catalytic DNA

- 11 -

molecule identified as 10-23. Also as required by the Examiner, Applicants hereby elect, with traverse, SEQ ID NO:108, corresponding to a nucleotide sequence complementary to said first and second substrate binding regions of the claimed catalytic DNA molecule.

Election of SEQ ID NO:121 is made with traverse because SEQ ID NO:121 is one species of a core region of a catalytic DNA molecule within the genus of core regions set forth by Formula II (SEQ ID NO:122) in the independent claims.

Election of SEQ ID NO:108 is made with traverse because SEQ ID NO:108 is one species of a substrate within the genus of substrates that can be targeted by the claimed catalytic DNA molecules.

3. Mischaracterization of the Invention

Applicants respectfully submit that the Examiner has mischaracterized the claimed invention in many respects in the present Action (paper no. 27); therefore, Applicants are making the following remarks to clarify the record.

The Examiner asserts at page 4, lines 4-5 and at page 4, lines 9-10 of the Action that the claimed catalytic DNA molecules "inhibit the expression of different proteins or cleave a target protein to a different degree", apparently implying that an action upon different proteins indicates separate inventions. Applicants respectfully submit that the claims do not recite inhibiting "the expression of different proteins" or cleaving "a target protein" and; therefore, the assertion is without merit.

The Examiner asserts at page 4, lines 28-30 of the Action that the, "instant catalytic DNA sequences, SEQ ID NO:102-121, and the formulas I and II (SEQ ID NO:122) are considered to be each separate inventions". Applicants respectfully submit that SEQ ID NOs: 102-119 are sequences that are complementary to the

- 12 -

first and second substrate binding regions of the claimed catalytic DNA molecules. Thus, SEQ ID NOs: 102-119 are not the claimed catalytic DNA molecules. Accordingly, the assertion at page 4, lines 28-30 of the Action that the "instant catalytic DNA sequences, SEQ ID NO:102-121" is a mischaracterization of the claimed invention in so far as SEQ ID NOs: 102-119 are concerned because SEQ ID NOs:102-119 are not catalytic DNA molecules. See, also, the Examiner's own acknowledgment of this mischaracterization at page 3, lines 1-3 of the Action.

The Examiner asserts at page 4, lines 38-41 that "Even catalytic DNAs targeting the same gene have a different activity in that they cleave at a different location within the RNA and have different levels of cleavage activity, and regulate expression of a protein to a different extent". Applicants respectfully submit that the Examiner is mischaracterizing the meaning of the "activity" of the claimed catalytic DNA molecules. The claimed catalytic DNA molecules all have the same activity, that being endonuclease activity. It does not matter which location within a substrate nucleic acid is cleaved, the activity is still an endonuclease activity. "Different levels of cleavage activity" means just that, that the levels, or amount, of activity may be different, but the activity is that of the same endonuclease activity. In addition, Applicants respectfully submit that the claims do not recite regulating "expression of a protein", therefore, the present assertion is a mischaracterization of the claimed invention.

The Examiner next asserts that "Each member of the class cannot be substituted, one for the other, with the expectation that the same intended result would be achieved". Applicants respectfully submit that the "intended result" of a catalytic DNA

- 13 -

molecule is the endonuclease cleavage of a substrate nucleic acid; therefore, each member of the class can be substituted, one for the other, with the expectation that the substrate nucleic acid will be cleaved.

The Examiner next asserts at page 5, first paragraph, that "although the catalytic DNAs have small regions in common (ie. stem region) the sequences do not meet the criteria of (B)(1), as they do not share, one with another, a significant common core structure". Applicants respectfully point to independent claims 1 and 29 each of which recite that the catalytic DNA molecule comprises a core region having a sequence according to Formula II. Thus, the catalytic DNA molecules of the present invention do meet the criteria of (B)(1), for example, in that they share a "core structure".

The restriction requirement for election of SEQ ID NOs: 102-119 should be withdrawn because the claimed catalytic DNA molecules meet the requirement of Section (f)(i)(a) of Annex B of the PCT Administrative Instructions subsection (A) in that all alternatives have the common activity of endonuclease activity and the claimed catalytic DNA molecules meet the requirement of subsection (B)(1) in that the common structure of a catalytic core domain defined by Formula II (SEQ ID NO:122) is present in all alternatives.

4. Mischaracterization of Art

The only alleged "prior art" cited by the Examiner is US Patent No. 6,361,941 to Todd et al., hereinafter the `941 patent. The `941 patent claims a priority date of March 27, 1998 whereas the present application claims a priority date of April 29, 1997 (as evidenced by the Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Filing under 35 U.S.C. 371 and the PCT Request, which are enclosed for the

- 14 -

Examiner's convenience). The claimed priority date on the Filing Receipt from the United States Patent and Trademark Office dated February 01, 2000 is incorrectly listed as April 29, 1998. A Request for Corrected Filing Receipt providing the correct priority date of April 29, 1997 is filed herewith. Therefore, the assertion that the '941 patent is allegedly prior art to the present application should be withdrawn because the '941 patent does not qualify as prior art.

CONCLUSION

Claims 1, 3-29 and 31-50 are currently pending. No new matter is being added as a result of this amendment. If the Examiner requires clarification or has questions regarding this matter, the Examiner is encouraged to contact the representative for the Applicants at the phone number listed below.

The Commissioner is hereby authorized to charge Deposit Account No. 19-0962, should any additional fees be required in this application.

Respectfully submitted,

Sept. 15, 2004
Date

Michael McCarthy
Michael McCarthy, Reg. No. 46,910

THE SCRIPPS RESEARCH INSTITUTE
10550 North Torrey Pines Road
Mail Drop TPC 8
La Jolla, California 92037
(858) 784-2937